

**Remarks**

The Office Action mailed 3 July 2003 has been received and reviewed. Claims 43 and 46-52 having been canceled, claims 1-2, 16-21, 35-36, 39, and 44-45 having been amended, and claims 53-65 having been added, the pending claims are claims 1-42, 44-45, and 53-65. Of the pending claims, claims 1-38 have been withdrawn from consideration.

The paragraph beginning at page 26, line 27 of the specification has been amended to correct a typographical error and to delete reference numerals 20, 30, and 40, which are not illustrated in Figure 1. The paragraph beginning at page 27, line 27 has been amended to correct a typographical error, thereby correctly reciting "loading chamber 62," which is supported, for example, by Figure 1 and the specification at page 27, lines 11-12.

Claim 39 has been amended to incorporate the language of dependent claim 43, now canceled. Claim 39 has also been amended to move recitations from the preamble to the body of the claim. Claim 39 has been further amended to recite "at least one distribution channel connecting the plurality of process chambers of the array," an amendment which is intended to clarify the claim, however the scope of the claim is intended to be the same or broader after the amendment as it was before the amendment. Finally, language in claim 39 has been cosmetically amended (i.e., "wherein at least one of the process arrays comprises a surface comprising an anion exchange material"). Claims 44 and 45 have been amended to depend from claim 39. Method claims 1-2, 17-18, 20-21, and 36 have been amended to incorporate recitations from device claim 39. Claims 16, 19, and 35, which depend from claims 2, 18, and 21, respectively, have been cosmetically amended in accordance with claims 2, 18, and 21, respectively (as amended). New claims 53-65 are supported, for example, by claim 39 and originally filed claims 4-14 and 17-18, respectively.

Reconsideration and withdrawal of the rejections are respectfully requested.

**Affirmation of Provisional Election**

Applicants thank the Examiner for withdrawing the Election of Species requirement. In the Office Action mailed 3 July 2003, the Examiner issued a rewritten Restriction Requirement under 35 U.S.C. §121 in the above-identified application, grouping the claims as follows: Group I, claims 1-38 drawn to methods of removing small negatively charged particles from a sample, Group II, claims 39-45, drawn to a device for removing small negatively charged particles from a sample, and Group III, claims 46-52, drawn to a container with an adhesive cover for removing small negatively charged particles from a sample. Applicants hereby affirm, with traverse, the election to prosecute claims 39-45, Group II.

Specifically, Applicants respectfully request that the Examiner reconsider the restriction requirement and rejoin Group II (claims 39-45, drawn to a device) with Group I (claims 1-38, as amended, drawn to methods of using a device). Applicants respectfully submit that that the inventions as claimed can be readily evaluated in one search without placing undue burden on the Examiner.

**Obviousness-Type Double Patenting Rejection**

Claims 39-45 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 53 and 56-61 of copending U.S. Pat. Application Serial No. 10/417,609. Claims 39-42 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 50-53 of copending U.S. Pat. Application Serial No. 10/027,226 in view of U.S. Pat. No. 6,344,326 (Nelson et al.). Upon an indication of otherwise allowable subject matter and in the event this rejection is maintained, Applicants will provide an appropriate response. In the event that the provisional obviousness-type double patenting rejections are the only rejections remaining in the present application, Applicants respectfully request that the Examiner withdraw

the provisional rejection and allow the application to issue as a patent pursuant to M.P.E.P. §804(I)(B).

### **Rejection under 35 U.S.C. §102**

The Examiner rejected claims 39-42 under 35 U.S.C. §102(e) as being anticipated by U.S. Pat. No. 6,344,326 (Nelson et al.). Applicants respectfully traverse the rejection.

Nelson et al. disclose "[i]ntegrated microfluidic devices comprising at least an enrichment channel (10) and a main electrophoretic flow-path (12). . . . In the subject integrated devices, the enrichment channel and the main electrophoretic flowpath are positioned so that waste fluid flows away from said main electrophoretic flowpath through a discharge outlet (6)." (Abstract). However, Nelson et al. lack, among other things, a disclosure or suggestion of a device that includes a plurality of process arrays wherein at least one of the process arrays comprises a surface comprising *an anion exchange material partially coated with a negatively charged polymer* (e.g., present independent claim 39).

Furthermore, the present invention discloses a device that is operable to *remove small negatively charged organic molecules* from a biological sample mixture (e.g., independent claim 39). As described in the present specification, "removal" of unwanted molecules involves adhering such molecules to the solid-phase material and allowing desirable products to remain in solution. This is in contrast to conventional elution methods that involve adhering the desirable products to the solid-phase material, washing away the unwanted molecules, and eluting the desirable products to remove them from the solid-phase material." (Specification at page 4, lines 25-30).

In contrast to the present invention, Nelson et al. suggest the use of ion exchange resins as "[s]uitable capture media for proteins" (column 8, lines 16-18). In short, Nelson et al. suggest conventional elution methods that involve that involve adhering the desirable products (e.g., proteins, column 8, lines 16-18) to the solid-phase material (e.g., ion exchange resins;

column 8, lines 16-18), (i.e., "enrichment;" column 2, lines 53-57), washing away the unwanted molecules (e.g., "waste fluid flows away from said main electrophoretic flowpath through a discharge outlet;" Abstract), and eluting the desirable products to remove them from the solid-phase material (e.g., "subsequent movement through the main electrophoretic flowpath;" column 2, lines 57-58).

Thus, for at least the reasons presented herein above, Applicants respectfully submit that claim 39 and dependent claims 40-42 are patentable over Nelson et al.

The Examiner also rejected claims 39 and 41 under 35 U.S.C. §102(b) as being anticipated by U.S. Pat. No. 6,450,047 (Swedberg et al.). Applicants respectfully note that Swedberg et al. issued on 17 September 2002, which is after the filing date of the present application, 20 December 2001. Thus, Swedberg et al. is not available as a reference under 35 U.S.C. §102(b). However, in the event that the rejection maintained, and to the extent that Swedberg et al. is available as art under 35 U.S.C. §102(e), Applicants respectfully traverse the rejection.

Swedberg et al. disclose a "microanalysis device having a plurality of sample processing compartments . . . for use in liquid phase analysis" (Abstract). Swedberg further state that "ion exchange separation may be effected in a separation compartment formed from a channel to which has been bonded, on which has been adsorbed or which has been coated with a member of a series of strong or weak anion or cation exchanger, or a combination of strong and weak anion or cation exchangers" (column 9, lines 28-33). However, Swedberg et al. lack, among other things, a disclosure or suggestion of a device that includes a plurality of process arrays wherein at least one of the process arrays comprises a surface comprising *an anion exchange material partially coated with a negatively charged polymer* (e.g., present independent claim 39). Thus, for at least the reasons presented herein above, Applicants respectfully submit that independent claim 39 and dependent claim 41 are patentable over Swedberg et al.

In view of the remarks presented herein above, Applicants respectfully request that the Examiner reconsider and withdraw the rejections under 35 U.S.C. §102.

### **Rejection under 35 U.S.C. §103**

The Examiner rejected claims 43-45 under 35 U.S.C. §103(a) as being unpatentable over U.S. Pat. No. 6,344,326 (Nelson et al.) in view of U.S. Pat. No. 6,265,168 (Gjerde et al.). Applicants respectfully traverse the rejection.

"To establish a *prima facie* case of obviousness . . . the prior art reference (or references when combined) must teach or suggest all the claim limitations." M.P.E.P. §706.02(j). Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness.

As described herein above, Nelson et al. lack, among other things, a disclosure or suggestion of a device that includes a plurality of process arrays wherein at least one of the process arrays comprises a surface comprising *an anion exchange material partially coated with a negatively charged polymer* (e.g., present independent claim 39).

Gjerde et al. disclose a "Matched Ion Polynucleotide Chromatography" (MIPC) separation method (column 5, lines 1-10). Gjerde et al. further disclose that "materials used currently in the MIPC column matrix of this invention, as well as other materials suitable for MIPC . . . are known to have an exceptionally high capacity and selectivity for long-chain nucleic acids" (column 30, lines 5-10). "Polymers having a negative charge may also be used provided *the charged groups are protonated to produce a neutral surface*" (column 30, lines 31-33; emphasis added). Thus, Gjerde et al. lack, among other things, a disclosure or suggestion of a device that includes a plurality of process arrays wherein at least one of the process arrays comprises a surface comprising *an anion exchange material partially coated with a negatively charged polymer* (e.g., present independent claim 39).

Thus, Applicants respectfully submit that Nelson et al. in view of Gjerde et al. fail to teach or suggest all the present claim language (e.g., claims 43-45, which depend from claim 39). In view of the remarks presented herein above, Applicants respectfully request that the Examiner reconsider and withdraw the rejections under 35 U.S.C. §103.

**New Claims**

New claims 53-63 depend from claim 39. New independent claims 64 and 65 recite the language of independent claim 39. For at least the reasons presented herein above for the patentability of independent claim 39, Applicants respectfully submit that new claims 53-65 are also patentable. Applicants respectfully request that the Examiner consider and pass new claims 53-65 on to allowance.

**Information Disclosure Statement**

Applicants originally submitted an Information Disclosure Statement on 26 April 2002. In a telephone conversation on 22 July 2003, the Examiner indicated that the documents listed on pages 3 and 4 of the 1449 forms could not be located. Applicants are submitting herewith clean copies of pages 3 and 4 of the 1449 forms, a copy of the Information Disclosure Statement submitted on 26 April 2002, copies of the documents listed on pages 3 and 4 of the 1449 forms, and a stamped postcard indicating receipt of the documents by the United States Patent and Trademark Office. Pursuant to the provisions of M.P.E.P. §609, Applicants further request that a copy of the 1449 form(s), marked as being considered and initialed by the Examiner, be returned with the next Official Communication.

**Request for Rejoinder**

Claims 1-38 (as amended) recite methods of using a device as recited, for example, in claim 39. Specifically, independent claims 1-2, 17-18, 20-21, and 36 recite language

**Amendment and Response**

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Serial No.: 10/027,222

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For: METHODS AND DEVICES FOR REMOVAL OF ORGANIC MOLECULES FROM BIOLOGICAL MIXTURES USING ANION EXCHANGE

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from independent claim 39. Upon an indication of claim 39 being allowable, Applicants respectfully request that the method claims (e.g., claims 1-38) also be examined and passed on to allowance pursuant to M.P.E.P. §821.04. *See, for example, In re Ochiai*, 71 F.3d 1565, 37 USPQ2d 1127 (Fec. Cir. 1995) and *In re Brouwer*, 77 F.3d 422, 37 USPQ2d 1663 (Fed. Cir. 1996).

**Summary**

It is respectfully submitted that all the pending claims are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for  
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**CERTIFICATE UNDER 37 CFR §1.10::**

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I hereby certify that the Transmittal Letter and the paper(s) and/or fee(s), as described hereinabove, are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR §1.10 on the date indicated above and is addressed to the Assistant Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

By: 

Name: SAM HER

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